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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,559	08/20/2001	Veerappa S. Subramanian	4961-5	6556

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	**PAPER NUMBER**
1615	9

DATE MAILED: 12/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/933,559	SUBRAMANIAN ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Acknowledgement of Papers Received: Request for Continued Examination received 9/24/03

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Lowey (USPN 4,680,323 hereafter referred to as '323), Baker et al (USPN 4,687,660 hereafter to as '660) and Seth (USPN 6,033,686 hereafter to as '686). The claims are again drawn to a solid dosage form of bupropion HCl. The dosage form is a sustained release tablet and the composition comprises carboxyvinyl polymer and microcrystalline cellulose or lactose. In addition the stabilization profile discussed above, after 2 weeks of storage at 55 degrees Celsius, there is at least 90% w/w of the bupropion remaining in the composition. The carboxyvinyl polymer provides a release profile where the drug is released from a period of 8 to 24 hours. Applicant recites a specific profile where the drug is release in a particular percentage

at a particular time (i.e. 30 – 45% within 1 hour, 60 – 80% in 4 hours, etc.). Claim 9 recites a method of stabilizing the drug comprising combining the constituents, and granulating with purified water.

'323 discloses a pharmaceutical tablet comprising pharmaceutically active agents, carboxyvinyl polymer and other cellulose derivates as excipients. Various classes of pharmaceutical agents are useful in the formulation including analgesics and bronchodilators (Abstract). The carboxyvinyl polymer allows for the active agents to be released over a 24-hour period (col. 3, lin. 55-60). The carboxyvinyl polymer is present in a concentration of from 1-90% (claims). What is lacking in the reference is a disclosure of the particular active agent, bupropion hydrochloride, and the other excipients recited by the claims, microcrystalline cellulose and/lactose.

'660 et al discloses a bupropion hydrochloride composition comprising water-soluble and insoluble polymers such as cellulose derivatives. The composition further comprises lactose (examples).

'686 however discloses a sustained release tablet comprising bupropion HCl, a water insoluble, water-permeable film-forming polymer and water-soluble polymer. The tablet releases 30 – 60% of the bupropion HCl after 1 hour, 55 – 80% after 2 hours, 75 – 95% after 3 hours, and 80 – 100% after 4 hours (col. 3, lin. 40 – 56). '686 also discloses a method of preparing the composition comprising mixing the constituents and granulating with purified water (examples). Though the reference does not explicitly claim this process as stabilizing, Seth's final product is a stable tablet.

With regard to applicant's limitation that the carboxyvinyl polymer is the sole stabilizing and control releasing material, it is the position of the examiner that this limitation cannot be given patentably weight without a showing of criticality. The combination proposed discloses a formulation comprising a carboxyvinyl polymer. Burden is shifted to applicant to provide the criticality to the carboxyvinyl polymer acting as the sole polymer. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

With these aspects in mind it would have been obvious to one of ordinary skill in the art to combine the teachings and suggestion of the art. A skilled artisan would have been motivated to combine the bupropion HCL of '660 into the formulation of '323 in order to impart stability and proper release of the agent. A skilled artisan would have been able to make the substitution since both references share excipients, active agents, and operate within the same field of endeavor. A skilled artisan would have been able to substitute the bupropion HCL of '660 into the formulation of '323, along with the lactose of the formulation in order the effect the release of the drug. Release profiles can be manipulated through concentrations of the non-active excipients, and is within the level of skill in the art. A skilled artisan would have further been motivated to combine the purified water and further excipients of '680 in order to better refine

the processing and release profile of the active agent. '680 releases bupropion HCL with ethyl cellulose as a possible excipient, similar to '660. A skilled artisan would have been motivated to make these combinations and substitutions in order to optimize the release of a bupropion HCL tablet. An expected result of such a combination would have been a tablet with a release profile and consistency useful as an anti-depressant.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is 703-746-7648.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MP Young

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600